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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/830,071

04/23/2004

Kishore M. Gadde

7687

7590

01/26/2007

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EXAMINER

ZHANG, NANCY L

ART UNIT

PAPER NUMBER

1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/830,071

Applicant(s)

GADDE ET AL.

Examiner

Nancy L. Zhang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8 sheets</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2006 has been entered.

### ***Response to Arguments***

Applicant's arguments filed 10/31/2006 have been fully considered but they are not persuasive.

Regarding claim rejections under 35 USC § 103(a) over Ayala in view of Shank (US Patent 6,071,537), both in view of Anderson et al. (US Patent 6,437,147) of claims 18-43,

Applicants argues that Ayala describes weight loss as an adverse effect of administering zonisamide to epileptic patients and a skilled artisan would not expect that the adverse events experienced by epileptic patients would result in positive benefits for obese patients.

The disclosure in Ayala abstract provides reasonable expectation of success for inducing weight loss in obese patients. Ayala discloses a study that followed 23 epileptic patients taking zonisamide to observe potential changes in body weight. The patients received zonisamide in amounts ranging from 200-700 mg/day (this dosage

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range is encompassed by applicant's claims). Fifteen of the 23 patients experienced a weight loss of 4-11% of total body weight. Three patients had weight loss of greater than 10%. Ayala additionally discloses that two of the three patients experiencing a weight loss of greater than 10% were being administered 600 mg/day, while the third was administered 700 mg/day. Ayala concludes by stating that zonisamide is associated with weight loss in some patients.

The observations disclosed by Ayala thus show that zonisamide is associated with weight loss in the epileptic patients. This would reasonably suggest to one of ordinary skill in the art that if zonisamide were administered to an overweight or obese patient, a reduction in weight would be observed. In other words, it would have been obvious and reasonable to conclude from Ayala's observations that since zonisamide is associated with weight loss, if effective amount (i.e. 200-700 mg/day) of zonisamide were administered to overweight patient, some loss in weight would result.

Ayala mentions that drug-related weight, in general, is considered an adverse event. However, more importantly, Ayala states that weight loss may be a problem in patients who are already below their ideal weights. Taken together, one of ordinary skill in the art would deduce that zonisamide induced weight loss would be an adverse event in a patient who is below his or her ideal weight. On the other hand, one of ordinary skill in the art would reasonably conclude that weight loss is not an adverse event in a patient who is obese. Finally, the examiner recognizes the difference between epileptic patients and obese patients. However, the weight loss observed by Ayala is not associated with the epileptic condition but is an effect from the administration of

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zonisamide. One of ordinary skill in the art would have no reason to conclude that zonisamide induced weight loss would not be observed in obese patients.

Regarding claim rejections under 35 USC § 103(a) over Coffin et al.(US PGPub 2001/0025038),

Applicant argues that Coffin et al. do not disclose or suggest the administration of “a pharmaceutical composition comprising zonisamide” for “reducing weight in an overweight subject”. The examiner disagrees. Coffin et al. teach a method for reducing cravings to food by administering a compound of “D<sub>1</sub>/D<sub>5</sub> antagonist or a D<sub>1</sub>/D<sub>5</sub> partial agonist or mixtures thereof”, and a compound of “an anticonvulsant” (Coffin et al., page 6, right column, claim 13) where the anticonvulsant can be zonisamide (page 5, right column, lines 3-5). Therefore, Coffin et al. disclose a “composition comprising zonisamide”, consonant with the claim language of the instant application. Regarding “reducing weight in an overweight subject”, by looking at the whole context of Coffin et al.’s disclosure, Coffin et al.’s treatment for reducing cravings to food is directed to treating obesity (page 1, left column, lines 6; page 3, Example 4; and page 4, Example 6) and therefore is directing to a method of reducing weight in an overweight subject.

The claim rejections under 35 USC § 103(a) made in the last office action are therefore maintained.

The Obviousness-type double patenting rejections made in the last office action are also maintained because the applicant has not filed a terminal disclaimer.

Claims 18-43 are pending and examined.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 18 and 35, the phrase "significant" and "sustained" render the claims indefinite because it is unclear as to what is considered as "significant" and "sustained", thereby rendering the scope of the claims unascertainable. See MPEP § 2173.05(d).

Regarding claims 25 and 42, the phrase "a hypocaloric diet" or "exercise" render the claims indefinite because it is unclear as to what is considered as "a hypocaloric diet" or "exercise", thereby rendering the scope of the claims unascertainable. See MPEP § 2173.05(d).

***Scope of Enablement Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing weight in an overweight patient by administering a pharmaceutical composition comprising zonisamide, does not

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reasonably provide enablement for treating eating disorders in a subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Claims 27-34 are drawn to a method of treating eating disorders in a subject comprising a pharmaceutical composition comprising zonisamide, in an amount effective to treat eating disorders.

The relative skill of those in the art of pharmaceuticals and the unpredictability of the pharmaceutical art is very high. In fact, the courts have made a distinction between mechanical elements function the same in different circumstances, yielding predictable results, chemical and biological compounds often react unpredictably under different circumstances. *Nationwide Chem. Corp. v. Wright*, 458 F. supp. 828, 839, 192 USPQ 95, 105(M.D. Fla. 1976); *Aff'd* 584 F.2d 714, 200 USPQ 257 (5th Cir. 1978); *In re*

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fischer, 427 F.2d 833, 839, 166 USPQ 10, 24(CCPA 1970). Thus, the physiological activity of a chemical or biological compound is considered to be an unpredictable art. Likewise, the physiological or pharmaceutical activity of treating "eating disorders" is also an unpredictable art.

Claims 27-34 are directed to the treatment of eating disorders by administering zonisamide.

The specification discloses example studies regarding the effects of weight reduction by administering zonisamide to obese patients. Although obesity may be related to an eating disorder, a method of treating obesity is not the same as a method of treating an eating disorder. The specification only demonstrates a limited number of working examples showing therapeutic studies of treating obese patient where zonisamide is effective in reducing weight in overweight patient. However, the specification has not provided any working example to support the claimed invention of claims 27-34 where zonisamide is effective in treating an eating disorder. Nor does the specification establish any convincing correlations or mechanisms of action for treating an eating disorder by administering said compound. Therefore, the skilled artisan would turn to undue amount of trial and error to find out which disease or condition would response to the administration of said compounds.

The examiner acknowledges that the Office does not require the presence of working examples to be present in the disclosure of the invention (see MPEP 2164.02). However, given the highly unpredictable state of the art and furthermore, given that the applicant does not provide sufficient guidance or direction as to how to make and use



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the full scope of the instant claimed invention without undue amount of experimentation, the Office would require appropriate disclosure, in the way of scientifically sound reasoning or the way of concrete examples, as to why the data shown is a reasonably representative and objective showing such that it was commensurate in scope with and, thus, adequately enables, the use of a cortisol inhibitor for the full scope of the presently claimed subject matter. In the absence of such guidance and evidence or reasoning, the specification fails to provide an enabling disclosure.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Jennings (US PGPub 2004/0029941, filing date: May 2, 2003; priority date: May 6, 2002).

Claims 18-43 are directed to a method of reducing weight or treating eating disorder comprising administering a pharmaceutical composition which comprises zonisamide where said weight loss is significant and sustained.

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Jennings teaches a method of treating overweight and obesity and eating disorders such as binge-eating disorders, bulimia nervosa and anorexia nervosa (see abstract). The method comprises administering to a subject a pharmaceutical composition comprising an effective amount of zonisamide and provides a sustained and significant weight loss in an overweight subject (see abstract).

Therefore, Jennings method of treatment anticipates the claimed invention.

The instant claims 19-20, 29-30 and 36-37 recite the limitation of dosage of zonisamide being about 100 to 600 mg/day; Jennings teaches the effective amount of zonisamide is in the range of about 100 to 600 mg/day (page 6, left column, claim 20).

The instant claims 22-23, 31-32 and 39-40 recite the limitation of the route of administration such as orally; Jennings teaches that the composition is administered orally (page 6, left column, claim 15).

The instant claim 24-26, 33-34 and 41-43 recite the limitation that the composition is administered in combination with another therapeutic method commonly used to reduce weight such as a hypocaloric diet or exercise or topiramate; Jennings teaches that the composition is administered in combination with another therapeutic method commonly used to reduce weight such as a hypocaloric diet or exercise or topiramate (page 6, right column, claims 24-26).

Therefore, claims 18-43 are clearly anticipated.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-21 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayala (already of record).

Claims 18-21 and 35-38 are directed to a method of reducing weight comprising administering to an overweight subject a pharmaceutical composition comprising zonisamide where said weight loss is significant and sustained.

Ayala teaches that the administration of zonisamide is effective in decreasing weight loss in patients. Ayala discloses a study that followed 23 epileptic patients taking zonisamide to observe potential changes in body weight. The patients received zonisamide in amounts ranging from 200-700 mg/day (this dosage range is

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encompassed by applicant's claims). Fifteen of the 23 patients experienced a weight loss of 4-11% of total body weight. Three patients had weight loss of greater than 10%. Ayala additionally discloses that two of the three patients experiencing a weight loss of greater than 10% were being administered 600 mg/day, while the third was administered 700 mg/day. Ayala concludes by stating that zonisamide is associated with weight loss in some patients.

Ayala does not teach that the weight loss is significant and sustained for treating an overweight subject. However, since the observations disclosed by Ayala show that zonisamide is associated with weight loss in the epileptic patients, it would have been obvious and reasonable to conclude from Ayala's observations that, if effective amount (i.e. 200-700 mg/day) of zonisamide were administered to an overweight patient, some loss in weight would result. Therefore, one having ordinary skill in the art would have been motivated at the time of the instant invention to administer zonisamide to an overweight patient for an effect of weight loss to result in the practice of the invention of claims 18-26 and 35-43 with a reasonable expectation of success.

Claims 22-23 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayala in view of Shank (US Patent 6,071,537) (already of record).

See rejections of claims 18-21 and 35-38 above. The modified method of claims 22-23 and 39-40 further limit that the administration of zonisamide is via orally route. Ayala does not teach that zonisamide is administered orally. However, the determination of the appropriate route of administering an active ingredient for a treatment is routinely made by those of ordinary skill in the art and is well within the

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ability of tasks routinely performed by them without undue experimentation. In addition, Shank discloses anticonvulsant derivatives such as topiramate useful in treating obesity where the active ingredient topiramate is prepared for oral administration (column 4, line 14). Thus, it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to determine oral administration as the route of administering zonisamide for the treatment.

Claims 24-26 and 35-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayala in view of Shank (US Patent 6,071,537) and Anderson et al. (US Patent 6,437,147) (both already of record).

See rejections of claims 18-21 and 35-38 above. The modified method of claims 24-26 and 35-43 further limit that the administration of zonisamide is combined with another therapeutic method commonly used to reduce weight such as a hypocaloric diet or exercise or another compound such as topiramate. Anderson et al. disclose a method of treating a disorder such as overweight or obesity (column 126, lines 27-26) by administration of a compound in combination with a hypocaloric diet or exercise (column 25, lines 66-67). Shank discloses anticonvulsant derivatives such as topiramate useful in treating obesity (see abstract and column 6, line 2). In re Kerkhoven (205 USPQ 1069, CCPA 1980) states that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been individually taught in the prior."

Claims 18-26 and 35-43 are rejected under 35 USC § 103(a) as being unpatentable over Coffin et al. (US PGPub 2001/0025038, pub date: Sep. 27, 2001) (already of record) in view of Shank (US Patent 6,071,537) and Anderson et al. (US Patent 6,437,147).

Claims 18-26 and 35-43 are directed to a method of treating obesity or eating disorder comprising administering to a subject a pharmaceutical composition comprising zonisamide.

Coffin et al. teach a method for reducing cravings to food by administering a compound of "D<sub>1</sub>/D<sub>5</sub> antagonist or a D<sub>1</sub>/D<sub>5</sub> partial agonist or mixtures thereof", and a compound of "an anticonvulsant" (Coffin et al., page 6, right column, claim 13) namely zonisamide (page 5, right column, lines 3-5). Thus, Coffin et al. disclose a "composition comprising zonisamide", consonant with the claim language of the instant application of "a pharmaceutical composition comprising zonisamide". In looking at the whole context of Coffin et al.'s disclosure, Coffin et al.'s treatment for reducing cravings to food is directed to treating obesity (page 1, left column, lines 6; page 3, Example 4; and page 4, Example 6) and therefore is directing to a method of reducing weight in an overweight subject. Therefore, Coffin et al.'s disclosure provides the skilled artisan with the necessary motivation and guidance to treat obesity or reduce weight gain in an individual in need thereof by reducing cravings for food in the individual.

Coffin et al. further teach that the components of the composition may be administered in any conventional oral dosage form (paragraph [0084], lines 12-14).

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Coffin et al. do not teach that the administration is combined with another therapeutic method commonly used to reduce weight such as a hypocaloric diet or exercise (as recited in claims 25 and 42) or another compound such as topiramate (as recited in claims 26 and 43). Anderson et al. disclose a method of treating a disorder such as overweight or obesity (column 126, lines 27-26) by administration of a compound in combination with a hypocaloric diet or exercise (column 25, lines 66-67). Shank discloses anticonvulsant derivatives such as topiramate useful in treating obesity (see abstract and column 6, line 2). In re Kerkhoven (205 USPQ 1069, CCPA 1980) states that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been individually taught in the prior."

Therefore, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the treatment of Coffin et al. in view of Shank and Anderson et al. to result in the practice of the instant invention of claims 18-26 and 35-43 with a reasonable expectation of success.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 7,109,198 (copending Application No. 10/440,404 of provisional obviousness-type double patenting rejection in previous Office Actions). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application No. 10/440,404 teach of treating obesity and hypertension (and diabetes or dyslipidaemia) with the administration of zonisamide or topiramate along with bupropion. These reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity.

The provisional rejection of claims 18-43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-34 of copending Application No. 11/058,981 is maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application No. 11/058,981 teach of treating obesity



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and hypertension (and diabetes or dyslipidaemia) with the administration of zonisamide or topiramate along with bupropion. These reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claims 18-43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-38 of copending Application No. 11/059,027 is maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application No. 11/059,027 teach of treating obesity and hypertension (and diabetes or dyslipidaemia) with the administration of zonisamide or topiramate along with bupropion. These reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claims 18-43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/034,316 is maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application No. 11/034,316 teach of treating obesity

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and hypertension (and diabetes or dyslipidaemia) with the administration of zonisamide or topiramate along with bupropion. These reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy L. Zhang whose telephone number is (571)-272-8270. The examiner can normally be reached on Mon.- Fri. 8:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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